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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,395	02/07/2001	Bernd Dorken	101195-38	2292

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NORRIS, MCLAUGHLIN & MARCUS, P.A.  
875 THIRD AVE  
18TH FLOOR  
NEW YORK, NY 10022

EXAMINER

VOGEL, NANCY S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/743,395

Applicant(s)

DORKEN ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/05 has been entered.

### ***Claim Objections***

Claims 19 and 24 are objected to because of the following informalities: In claim 19, presumably the words "increased level of expression" are intended to be deleted; in claim 24, an article is missing before the term "tumorigenic cell". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nabel (WO 97/11720 (previously cited)).

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 8/25/04, with slight modifications.

To recapitulate, Nabel et al. teach a method comprising the steps of preparing a transfected mammalian cell by transferring into said cell a first polynucleotide comprising a promoter operably linked to the coding sequence of p21, and a second polynucleotide comprising a promoter operably linked to a coding sequence (see pages 3-6 and 11-12, and claim 10). The polynucleotides may be an adenoviral vector (page 6). Nabel et al. disclose the method both in vitro and in vivo (see page 12-15 and pages 17-25, and claims). Nabel et al. disclose the method in a primary cell line or established cell line, including tumorigenic and non-tumorigenic cells (page 12-13, page 22-23). Nabel disclose the method in a human cell, or any mammal, which includes rodents, in vivo (see claims and page 11, lines 17-18). Absent evidence to the contrary, it is assumed that a method comprising the same steps as recited in the claimed method will achieve the same purpose, by the same mechanisms.

Applicant's arguments submitted 2/23/05 have been considered but have not been found convincing.

Applicant has argued that since the independent claim 15 has been amended to read "the stable transfer of genetic material results in enhanced expression levels of the second polynucleotide", the rejection should be withdrawn. However, it is maintained that since Nabel et al. discloses the identical method steps, i.e. transfecting a mammalian cell by transferring into said cell a genetic therapeutic, and the gene encoding p21 (see claim 10, see pages 11-12), any result such as improved stability or expression as recited in the instant claims, would have been obtained using the teachings of Nabel et al. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained essentially for the reason made of record in the previous Office action, mailed 8/25/04.

In response, applicants have argued that "The Examiner has not specifically indicated why the scope of cells should be limited and why the specification does not provide guidance to persons in the art, sufficient enough to practice the invention" (page 8 of the arguments). However, it is maintained that the previous Office action did contain sufficient explanations of why the specification does not provide adequate description such that one skilled in the art could make and/or use the invention. The explanation included such factors as unpredictability in the art, as shown by the disclosures of Kondo and Kokunai, which have shown different and unpredictable results when p21 is expressed in different cell types. Applicants have not addressed these arguments in their present response. Therefore, the rejection is maintained.

Claims 20, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 8/25/04, and originally made in the Office action mailed 2/10/04.

To recapitulate, the specification as originally filed does not provide support for the invention as now claimed: "wherein the mammalian cell is an established cell line or a primary culture" (claim 20); "wherein the mammalian cell is a rodent cell" (claim 22); "wherein the mammalian cell is tumorigenic" (claim 24)' "wherein the improved stability results from the p21-mediated inhibition of cytotoxicity" (claim 26). This a new matter rejection. The specification does not provide sufficient blazemarks or direction for the instant methods encompassing the above-mentioned limitations, as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

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Applicants have argued that 'one skilled in the art would know that the terms "cultured cells, primary cells, and in vivo," encompasses mammalian cells, rodent cells'. However, it is maintained that the generic recitation of mammalian cells does not provide adequate support for the claims which has been added and which specify that the cells are "established cell line or a primary culture", rodent cells, or that improved stability results from p21 mediated inhibition of cytotoxicity. There is no disclosure of these limitations in the specification as originally filed, and the specification does not provide an adequate description of these embodiments. Therefore, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25 and 26 recite the limitation "the improved stability" in line 1. There is insufficient antecedent basis for this limitation in the claim on which claims 25 and 26 are dependent, i.e. claim 1. Therefore, the claims are unclear and the intended subject matter cannot be determined.

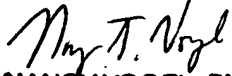
### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**NANCY VOGEL, PH.D.**  
**PATENT EXAMINER**